Bioprocessing Systems Services

Millipore®

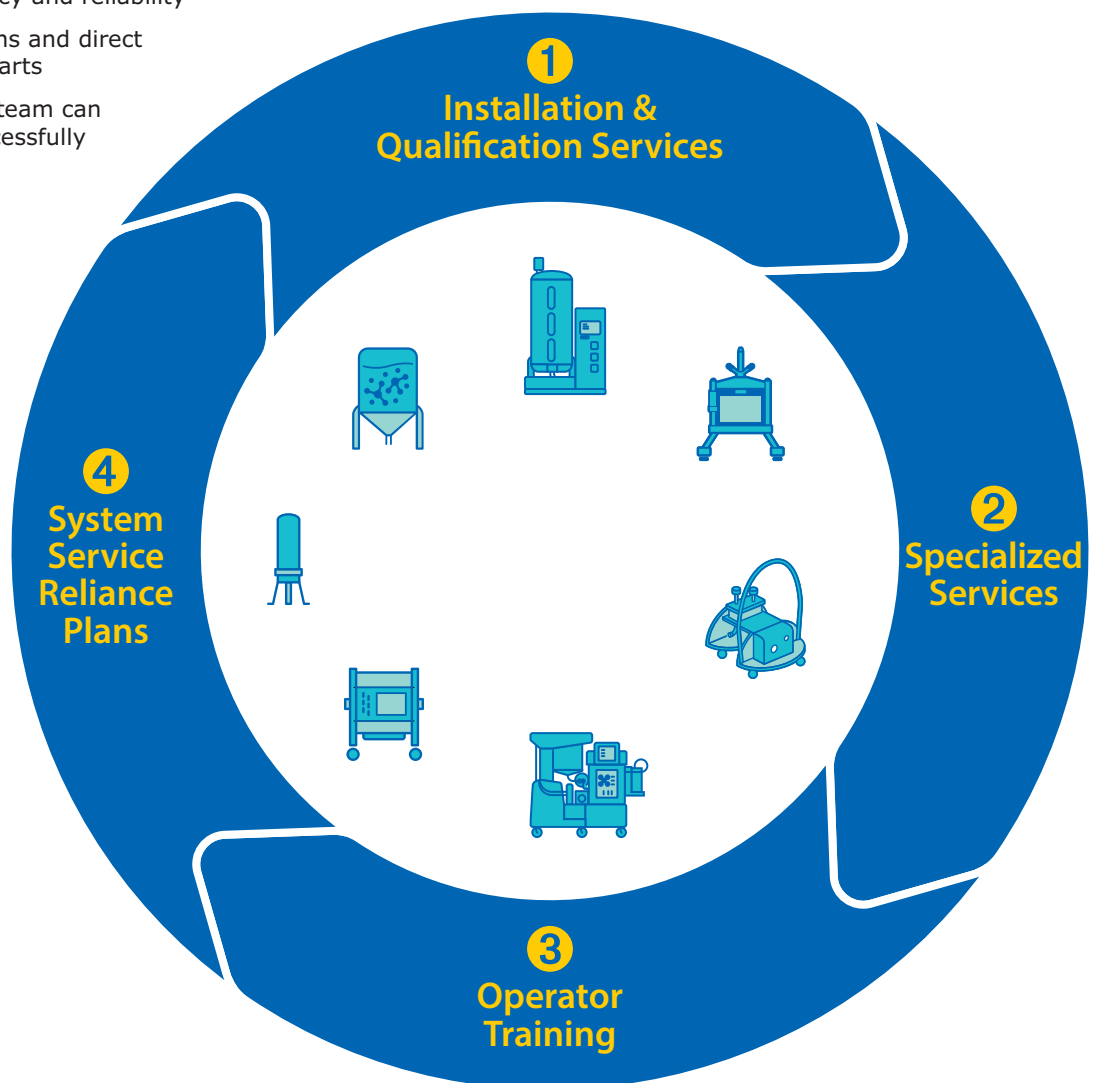Preparation, Separation, Filtration & Monitoring Products

Bioprocessing Systems Services

Maintain your validated system performance with a priority access to support, speed up implementation, and increase the lifetime of your system

To help you navigate the highly regulated and complex biopharmaceutical industry, we offer a wide range of best-in-class, comprehensive services to meet your unique manufacturing requirements. Our suite of services provides you with support through all stages of your system's life-cycle, from the installation and qualification, to the training and maintenance needed to keep your equipment running smoothly and efficiently. All our services are performed by our global experts who have unique intimate knowledge of our equipment, backed by years of experience.

Benefits

- Enable smooth, successful, and fast implementation and integration of systems
- Maintain validated systems performance
- Increase system efficiency and reliability
- Receive recommendations and direct access to replacement parts
- Training to ensure your team can operate the system successfully

① Installation & Qualification Services

② Specialized Services

③ Operator Training

④ System Service Reliance Plans

Installation and Qualification

Seamless integration of our systems into your process

We understand the pressure you face to get your new equipment up and running as quickly as possible, while ensuring it meets all regulatory requirements. Through our offering of installation and qualification services, our experienced engineers will partner with you to ensure your equipment is installed, qualified and operational to your requirements.

Factory Acceptance Testing (FAT)

With our FAT service, your equipment is fully tested for compliance with technical and quality specifications prior to shipment. Performance of an FAT will also yield test reports that can be used throughout the remaining IQ/OQ qualification stages.

Installation Qualification/Operational Qualification (IQ/OQ)

Our IQ/OQ service ensures your system is fully documented, operational, compliant to pharmaceutical manufacturing requirements, and ready for your PQ.

Full Test Package

This service is an alternative to standard IQ/OQ services for customers who wish to have tests from FAT repeated at their site.
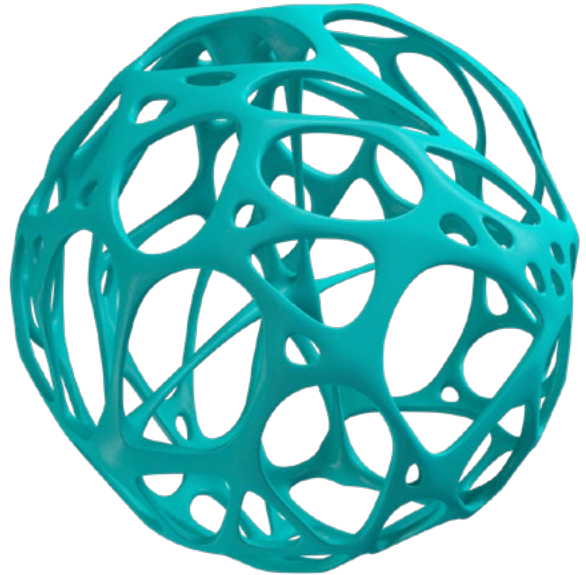
What we provide:

FAT static and dynamic tests:

- Review of executed release tests
- Visual inspection
- Mechanical test
- Electrical test
- Automation test
- Completion of system documentation

IQ/OQ includes static and dynamic tests:

- Completion of as-built system documentation
- Visual inspection
- Mechanical tests
- Electrical tests
- Instrumentation verification
- Functional tests

Performance Qualification (PQ)

Performing the qualification of your entire process with new equipment can be challenging and time consuming. Our biomanufacturing engineers are ready to help you with our performance qualification support. With this service, an engineer will come on-site to assist you while you perform your qualification, including assistance with system set up, dry runs, engineering runs, and even process runs.

Specialized Support

Services to meet your specific needs

To help you manage the frequently changing needs and requirements of the biopharmaceutical manufacturing industry, we offer additional specialized support services so you never feel alone in managing your system.

Application Support

Our consultants are available to support you throughout your product's life-cycle, either remotely, in one of our nine M Lab™ Collaboration Centers, or at your site. We are there to help from the early phases of evaluating your system application and needs, to the later stages of validation and preliminary runs. As your manufacturing capacity grows, our experienced personnel can also provide scale-up support.

Our team will:

Provide guidance and best practices to support your process development, scale-up and technology transfer activities:

- Define the best product for your needs
- Speed up validation and implementation
- Support your column packing requirements

We will concentrate on the solutions, so you can concentrate on innovation and the future.

CCP® Software Recipe Design

Every process is unique and, to ensure that your system is optimized to deliver the best performance, our biomanufacturing engineers will configure CCP® software recipes for your specific process. This allows your system to run fully automatically, resulting in consistency and reduced operator error.

Gradient Testing

In order to check mixing efficiency, linear and step gradient tests will be performed, and gradient accuracy will be verified using standard or customer conditions.

Operator Training

Everything your team needs to know

Appropriate training for your users is not only a Good Manufacturing Practices requirement, it also ensures your staff has the knowledge and expertise to operate and manage the system as part of your manufacturing process.

Operator Training

Good Manufacturing Practices require users to receive appropriate training and certification on all new equipment. Through our operator trainings, hands-on sessions are available to satisfy GMP requirements and course graduates receive a certificate upon completion.

CCP® Software Training

If your system will be used for process development, it may need to be adapted to operate efficiently with varying process characteristics. Our biomanufacturing engineers can provide you with specialized training, including a hands-on session, so that you are able to create and manage your own recipes. This service will enable a more autonomous staff that can manage the system and process efficiently and independently.

Based on your operators' needs and experience, we offer several CCP® software training options:

	CCP® Software V.6 Training*	System Use, Troubleshooting, and CCP® Software V.6 Training*	System Use, Process Design, Troubleshooting, and CCP® Software V.6 Training**
	Duration: 1.5 days	**Duration: 3 days**	**Duration: 4.5 days**
Introduction and system overview	✓	✓	✓
System installation	✗	✓	✓
Human machine interface (HMI) overview	✓	✓	✓
Manual control of the system	✗	✓	✓
System dismounting	✗	✓	✓
Recipe editor tool and batch reporting	✓	✓	✓
Process control	✗	✓	✓
Troubleshooting based on cases	✗	✓	✓
Troubleshooting based on reports	✗	✓	✓
Programming basics	✓	✓	✓
Recipe writing session	✓	✓	✓
Water runs and recipe fine-tuning	✗	✗	✓
Assessment and correction	✓	✓	✓
Wrap up	✓	✓	✓
Recommended audience	**Supervisors and engineers**	**Operators, supervisors, and engineers**	**Operators, supervisors, and engineers**

* For this training, participants should have already attended the operator training

** This training session is accessible only to customers who have chosen CCP® software recipe design service

System Service Reliance Plans

Maintain your validated system performance with a priority access to support

To ensure optimum equipment uptime and to mitigate the risk that the equipment doesn't meet the validated performance specifications, we have developed System Service Reliance Plans; a complete range of services for your systems and equipment. These three comprehensive service and support packages allow you to select a coverage level that best fits your needs.

All services are performed by our global experts who have intimate knowledge of our equipment, backed by decades of experience.

Preventive Maintenance (PM)

Included in all coverage levels, our preventive maintenance yearly visit ensures your equipment is maintained and verified using established protocols, enabling documented compliance with quality requirements. Spare parts, which must be purchased separately, will be replaced as needed. Maintenance recommendations and a full report of the services performed will also be provided to ensure that the validated state of the equipment is maintained.

Remote and On-Site Troubleshooting

In the unlikely case your system does experience a problem, our engineers will provide remote or on-site technical support to get you back up and running as quickly as possible. Our Advanced and Total Reliance Plans includes digital solutions such as smart glasses and remote connection, to ensure rapid and efficient troubleshooting.

Spare Parts

Our System Service Reliance Plans also include a spare parts advisory service, providing you with recommendations on parts to have in stock, based on our experience. Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time. All spare parts are manufactured within the same production facilities as your system, ensuring the same quality level as the original. Check out our illustrated spare parts lists on our website **sigmaaldrich.com**.

System Service Reliance Plans coverage levels

Services	Details	Protection Level → Risk Level		
		Total Reliance Plan	**Advanced Reliance Plan**	**Essential Reliance Plan**
System Eligibility		**<10 years**	**<15 years**	**All ages**
Preventive Maintenance (PM) visit	1 PM visit (labor and travel included)[a]	✓	✓	✓
Preventive Maintenance (PM) spare parts kit	Yearly preventive maintenance spare parts kit	✗	✗	✗
Traceable and auditable documentation	Full service report	✓	✓	✓
Spare parts storage assessment	Spare part advisory service (first year only)	✓	✓	✓
Asset tagging solution	QR code sticker and cards	[QR] ✓	[QR] ✓	[QR] ✓
Remote troubleshooting	Priority remote support on system and software[b]—phone and email	24 h[e]	24 h[e]	✓
	Priority remote support on system and software[b]—smart glasses and remote connection[c]	[smart glasses] ✓[f] [remote connection]	[smart glasses] ✓[f] [remote connection]	✗
On-site troubleshooting	On-site support—response time	Within 48 h[g]	Within 5 days[g]	No engagement on response time
	Troubleshooting/repair visit (labor and travel included)	Unlimited	1 per year (no carry over)	Billable services
Spare parts	Spare parts for repair[d]	Included	15% discount[h]	10% discount[h]

[smart glasses icon] = Smart Glasses   [remote connection icon] = Remote connection   [QR icon] = Asset Tagging

(a) Maintenance kit to be purchased separately prior to service.

(b) Support provided via phone and email and limited to 10 cases per year and 30 h of investigation. Software update not included in System Service Reliance Plans.

(c) Only for suitable systems and if the connection is tested upfront with customer.

(d) Best effort is aimed at supplying spare parts and/or find equivalent over the system's lifetime, but no guarantee of availability over time.

(e) 24h from the customer's requests, to our service team returning the call. May vary depending on customer's location.

(f) Smart glasses eligibility: for number of service plans ≥3 large systems and ≥5 small systems (Integritest® 5 System, Mobius® MIX System, Mobius® Power MIX System). 1 pair of smart glasses per customer. Additional pair will be charged.

(g) Five business days for Advanced, or 48 business hours for Total, from the time when it is agreed that a troubleshooting visit is necessary.

(h) Discount on list price.

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EMDMillipore.com/Systems-Services

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